

Amendment and Response

Applicant: Mark Shu et al.

Serial No.: 10/792,186

Filed: March 3, 2004

Docket No.: M190.148.101 / P0011480.00

Title: SUTURE LOCKING ASSEMBLY AND METHOD OF USE

REMARKS

This is responsive to the Non-Final Office Action mailed October 15, 2008. In that Office Action, claims 1-11, 13-31, 54, 55, 57, and 58 were rejected under 35 U.S.C. §102(b) as being anticipated by Purdy et al., U.S. patent No. 5,562,729 ("Purdy"). Claims 1-31, 54, 55, 57, and 58 were also rejected under 35 U.S.C. §102(b) as being anticipated by Sauter et al., U.S. Patent No. 5,071,431 ("Sauter"). Claim 12 was rejected under 35 U.S.C. §103(a) as being unpatentable over Purdy. The Examiner's indication that claim 56, although objected to, would be deemed allowable if rewritten, is noted with appreciation.

With this Response, claims 51-53 have been withdrawn, and claims 1 and 55 have been amended. Claims 1-31 and 51-58 remain pending in the application and are presented for reconsideration and allowance.

Restriction Requirement

In response to the Restriction Requirement mailed June 11, 2008, Applicant elected the Examiner-identified invention of Group I (claims 1-31 and 54-58) with traverse (Election filed July 11, 2008). The current Office Action does not address Applicant's traverse of the Restriction Requirement, and provides no indication as to the current status of the claims of unelected Group II (claims 51-53). Applicant respectfully requests review of Applicant's traversal of the Restriction Requirement. For the sake of completeness, claims 51-53 have been indicated as "withdrawn" with this Response; however, Applicant reserves the right to designate claims 51-53 as "currently pending" subject to review of the Restriction Requirement traversal.

35 U.S.C. §§102, 103 Rejections***Rejections Based on Purdy***

As argued in previous Responses, claim 1 recites, amongst other things, a suture locking assembly "configured to securely maintain a suture segment that is circumferentially pulled relative to at least one of the flanges from a first position to a second position". The Office Action asserts that the language in question is functional, stating that "the Examiner has given

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weight to the wherein clause, but the Examiner has to only look for a suture locking assembly that is capable of being pulled relative to at least one flange.” While Applicant concurs that the language in question may be functional in nature, the appropriate analysis is not whether the “suture locking assembly” is in and of itself capable of being pulled relative to a flange, but rather whether the alleged prior art suture locking assembly is capable of securing a suture segment that is circumferential pulled from a first position to a second position. In other words, the question of whether a prior art suture locking assembly is circumferentially transitionable or pullable has no bearing on the features of claim 1; instead, the question is whether an alleged suture locking assembly in the prior art is capable of maintaining a circumferentially pulled suture segment. In this regard, Applicant agrees that a “suture segment” is not a positive limitation of claim 1; however, a suture locking assembly capable of securing a suture segment in the manner claimed must still be identified in the prior art in order to anticipate claim 1. As described below, it is respectfully submitted that Purdy does not provide such a teaching.

In particular, the Office Action interprets the stent ring 202 of Purdy as being the “rim” of claim 1, and the unnumbered suture in FIG. 35 as being the claimed “suture band”. This so-identified “suture locking assembly” is not capable of securely maintaining a separate suture segment that is circumferentially pulled relative to the rim flanges. More particularly, the purported “suture locking assembly” of Purdy does not provide first and second positions relative to which a separate suture segment could be circumferentially pulled and securely maintained. Thus, claim 1 is allowable over Purdy.

Notwithstanding the above, and in an effort to expedite prosecution, claim 1 has been amended to recite that relative to a circumferential interface between the rim and the suture band, a radial spacing between the rim and the suture band decreases from a first radial spacing to a second radial spacing, the second radial spacing being circumferentially adjacent the first radial spacing. Further, the claimed “first and second positions” are relative to the first and second radial spacings, respectively. Support for this language is found, for example, in FIGS. 32, 34A, and 34B (with FIG. 34B illustrating a decreased radial spacing between the rim 320 and the suture band 370 relative to the radial spacing of FIG. 34A); as well as FIGS. 36-42. In contrast,

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a radial spacing between the rim/stent ring 202 and the suture band/suture (unnumbered) of Purdy is uniform along an entirety of the circumferential interface. The embodiment of Purdy FIGS. 4-4B (identified in the Office Action as also implicating claim 1) is similarly limited. Thus, because Purdy does not teach or reasonably make obvious the first and second radial spacings of amended claim 1, amended claim 1 is allowable over Purdy.

Claims 2-31, 54, 55, 57, and 58 depend from claim 1 and thus, for at least the above reasons, are allowable over Purdy. Additional distinctions exist that have not been addressed by the Office Action. In this regard, while the Office Action provides a brief explanation as to the rejections of claims 2, 3, 8, 9, 11, and 13, the features of the remaining dependent claims have not been addressed. In the event the Examiner determines that a second Office Action is necessary, it would be improper for this second Office Action to be made final as the current Office Action does not fully examine all claims.

For example, claim 4 recites that the rim defines a plurality of recesses. The Office Action fails to identify any corresponding features in FIGS. 4-4B or 34-37 of Purdy, and none exist. Complete examination of claim 4 is respectfully requested.

Claim 7 recites that the rim defines a plurality of segments, with each segment defining a recess. The Office Action fails to identify any corresponding features in FIGS. 4-4B or 34-37 of Purdy, and none exist. Completely examination of claim 7 is respectfully requested.

Claim 16 recites that the suture locking assembly is configured to be positioned adjacent a sewing ring of the heart valve repair device. These features of claim 16 are not specifically examined in the Office Action; in fact, these features are not taught by Purdy as the purported “suture locking assembly” of Purdy is the sewing ring of the heart valve repair device. Complete examination of claim 16 is respectfully requested.

Claim 20 recites a plastic cover attached to the suture locking assembly opposite the rim. The Office Action fails to identify any of the corresponding features in FIGS. 4-4B or 34-37 of Purdy, and none exist. Complete examination of claim 20 is respectfully requested.

Claim 54 recites that a perimeter shape of the first flange differs from a perimeter shape of the second flange. The Office Action fails to identify any corresponding features in Purdy,

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and none exist. In fact, the flanges 204 of the rim/stent ring 202, as well as of the rim/stent ring annulus 19, have identical perimeter shapes, as do all other embodiments. Complete examination of claim 54 is respectfully requested.

Claim 55 recites that the first and second flanges form differing, first and second patterns of radial indentations. The Office Action fails to identify corresponding features in Purdy, and none exist. For example, the flanges 204 of the rim/stent ring 202 do not form radial indentations, let alone differing patterns; the rim/stent ring annulus 19 is similarly limited. Complete examination of claim 55 is respectfully requested.

Claim 57 recites that the rim forms a plurality of recesses and that each of the recesses are non-symmetrical. The Office Action fails to identify corresponding features in Purdy, and none exist. The rim/stent ring 202 does not form any recesses, let alone none-symmetrical recesses; the rim/stent ring annulus 19 is similarly limited. Complete examination of claim 57 is respectfully requested.

Claim 58 recites that the recesses of claim 57 are defined by a leading surface and a trailing surface, and further that an angle of extension of the surface relative to a lateral edge differs. The Office Action fails to identify any corresponding teaching in Purdy, and none exist. For example, the rim/stent ring 202 does not form a plurality of recesses, let alone recess surfaces of different extension angles. The rim/stent ring annulus 19 is similarly limited. Complete examination of claim 58 is respectfully requested.

Rejections Based on Sauter

In rejecting claim 1 as being anticipated by Sauter, the Office Action interprets the annular valve body 16 as being the claimed “rim”, and the stiffening ring 24 as being the claimed “suture band”. Based upon the Office Action’s statement of “wherein a portion of the flange [of the suture band/stiffening ring 24] is capable of engagement with the annular flange of the frame [rim/valve body 16]”, it is believed the Examiner is asserting that because one of the suture band/stiffening ring 24 flanges could hypothetically “fit” within the groove 22 of the rim/valve

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body 16, the features of claim 1 are met. Applicant respectfully disagrees for at least the following reasons.

First, to anticipate claim 1, Sauter must disclose a suture band maintained between flanges of a rim; the Office Action's reference to a device "capable of the claimed configuration" is incomplete and cannot anticipate the claim language. Also, nothing in Sauter teaches the hypothetical arrangement asserted by the Office Action. To the contrary, the groove 22 formed by the rim/valve body 16 is occupied by the separate locking ring 32, and not the suture band/stiffening ring 24 (*see, FIG. 3*). Further, as made evident by FIG. 4, the structural features of the rim/valve body 16 and the suture band/stiffening ring 24 are such that the flanges of the suture band/stiffening ring 24 could not nest within the groove 22 of the rim/valve body 16. Because the vertical distance between the groove 22 and the corresponding end of the rim/valve body 16 is greater than a vertical distance between adjacent flanges of the suture band/stiffening ring 24, in no instance will a flange of the suture band/stiffening ring 24 nest within the groove 22 upon assembly of the components 16, 24. Thus, Sauter does not teach a suture band maintained between the first flange and the second flange of the rim as claimed.

Second, the purported "suture locking assembly" of Sauter is not configured to securely maintain a separate suture segment that is circumferentially pulled from a first position to a second position. As described above, the Examiner has agreed that in order for Sauter to teach these claimed features, the device of Sauter must be capable of meeting the claimed features. The Office Action fails to address this requirement, and in fact Sauter does not provide such a teaching. Instead, while a suture might theoretically be maintained between the rim/valve body 16 and the suture band/stiffening ring 24, the so-positioned suture segment could not be circumferentially pulled from a first position to a second position at which the suture segment would be securely maintained. Thus, claim 1 is further novel over Sauter.

Third, Sauter does not teach the first and second radial spacings of amended claim 1. For example, as shown in FIG. 3, relative to a circumferential interface between the rim/valve body 16 and the suture band/stiffening ring 24, a uniform radial spacing is established. While the radial spacing between the components 16, 24 may vary relative to a height thereof, amended

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claim 1 correlates the differing radial spacings relative to a circumference of the interface. Thus, the radial spacing features of amended claim 1 are not met by Sauter.

For at least the above reasons, claim 1 is allowable over Sauter. Claims 2-31, 54, 55, 57, and 58 depend from claim 1 and are thus also allowable over Sauter. Additional distinctions exist. In this regard, the Office Action fails to provide any explanation as to how features of the dependent claims are anticipated by Sauter. Complete examination of the dependent claims is respectfully requested. In the interest of brevity, Applicant asserts that at least dependent claims 4-9, 14, 16, 20, 24, 27-31, 54, 55, 57, and 58 recite features not taught or reasonably made obvious by Sauter.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-31 and 51-58 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-31 and 51-58 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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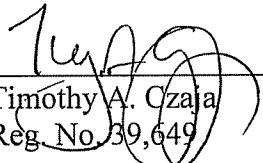
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Respectfully submitted,

Mark Shu et al.,

By their attorneys,

Date: January 15, 2009
TAC:jms



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